

17. The method of claim 7 wherein the lipid-soluble *Echinacea* extract is *Echinacea purpurea* extract.
18. The method of claim 7 wherein the lipid-soluble *Echinacea* extract is an effective amount to induce phase II enzyme expression (i) ✓
- B2 19. The method of claim 7 wherein the lipid-soluble *Echinacea* extract is about 0.09 mg/ml
20. The method of claim 8 wherein the phase II enzyme has a quinone reductase activity of about 1.86 at 610 nm. inherent

Remarks

Upon entry of the above amendments, Claims 7-11 and 17-20 are pending in this application. Please cancel Claims 1-6 and Claims 12-16 without prejudice. Claims 17-20 have been added. Support for Claims 17-20 is found on page 9, lines 5 and 6 and lines 14-24; and Fig. 2. No new matter has been added by the amendments. By way of the above amendments and the following remarks, Applicants believe all pending claims are in condition for allowance.

Examiner rejected Claims 7-11 under 102(b) as unpatentable over Facino. Facino does not anticipate the present invention because Facino fails to teach Claim 7 as amended. In particular, Facino does not disclose that lipid-soluble portions of *Echinacea* extract are administered to subjects in need of phase II enzyme induction. Rather, Facino suggests that chloroform-soluble portions of *Echinacea* are administered to humans to inhibit hyaluronidase activity. Accordingly, Applicants request removal of this rejection.

Examiner rejected Claims 7-11 under 103(a) as being unpatentable over Facino in view of Braswell. Facino and Braswell do not make any mention of the induction of phase II enzyme let alone induction of phase II enzyme by administering to subjects in need thereof a lipid-soluble *Echinacea* extract. In Facino, the administration of chloroform-soluble *Echinacea*

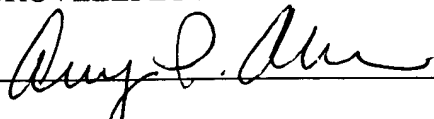
extract is to inhibit hyaluronidase activity. In Braswell, the administration of *Echinacea* extract is for immunostimulation, namely, bacterial stimulation in the oral cavity. It would not have been obvious to one of ordinary skill in the art to refer to the primary reference, Facino, and expect that administering a lipid-soluble *Echinacea* extract to a subject would induce phase II enzymes. Hyaluronidase does not belong to the class of phase II enzymes, which include quinone reductase and glutathione S-transferase. Further, hyaluronidase and phase II enzymes affect different biological functions. While hyaluronidase is believed to be involved in the migration of cells, phase II enzymes are involved in detoxification. Accordingly, Applicants request removal of this rejection.

Applicants believe the pending claims are in condition for allowance. If, for any reason, Examiner feels that the above amendments and remarks do not put the claims in condition for allowance, please contact the undersigned attorney to resolve any remaining issues.

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Respectfully Submitted,

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Appendix

7. (Once Amended) A method of inducing the expression of a phase II enzyme in a subject in need thereof comprising administering to the subject a lipid-soluble *Echinacea* extract.
 17. (New) The method of claim 7 wherein the lipid-soluble *Echinacea* extract is *Echinacea purpurea* extract.
 18. (New) The method of claim 7 wherein the lipid-soluble *Echinacea* extract is an effective amount to induce phase II enzyme expression.
 19. (New) The method of claim 7 wherein the lipid-soluble *Echinacea* extract is about 0.09 mg/ml.
 20. (New) The method of claim 8 wherein the phase II enzyme has a quinone reductase activity of about 1.86 at 610 nm.
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